CLAIMS

1. A stable G-CSF formulation having a residual ratio of G-CSF of 90% or more after long-term storage testing at 25°C for 3 months or a residual ratio of G-CSF of 90% or more after long-term storage testing at 40°C for 2 months or a residual ratio of G-CSF of 90% or more after accelerated testing at 50°C for 1 month or a residual ratio of G-CSF of 90% or more after accelerated testing at 60°C for 2 weeks and a content of Met-oxidized G-CSF of 1% or less after accelerated testing at 50°C for 1 month or after accelerated testing at 60°C for 2 weeks.

2. The G-CSF formulation of Claim 1 containing one or more amino acids selected from the group consisting of lysine, histidine, arginine, aspartic acid, glutamic acid, threonine and asparagine; one or more amino acids selected from hydrophobic amino acids; and methionine.

3. The G-CSF formulation of Claim 2 wherein said hydrophobic amino acid is selected from phenylalanine, tryptophan and leucine.

4. The G-CSF formulation of Claim 1 containing one or more amino acids selected from the group consisting of lysine, histidine, arginine, aspartic acid and glutamic acid; one or more amino acids selected from the group consisting of phenylalanine, tryptophan and leucine; and methionine.

5. The G-CSF formulation of Claim 1 containing phenylalanine, arginine and methionine.

6. The G-CSF formulation of any one of Claims 1 to 5,

which is substantially free from protein as a stabilizer.

7. The G-CSF formulation of any one of Claims 1 to 6 in the form of a lyophilized formulation.

8. The G-CSF formulation of any one of Claims 1 to 7 further containing mannitol.

9. The G-CSF formulation of any one of Claims 1 to 8 further containing a surfactant.

10. The G-CSF formulation of Claim 9 wherein said surfactant is a polyoxyethylene sorbitan alkyl ester.

11. The G-CSF formulation of Claim 10 wherein said surfactant is Polysorbate 20 and/or 80.

12. The G-CSF formulation of any one of Claims 1 to 11, which has a pH of 5-7.

13. The G-CSF formulation of Claim 12, which has a pH of 5.5-6.8.

14. The G-CSF formulation of Claim 13, which has a pH of 6.5.

15. The G-CSF formulation of any one of Claims 1 to 14 wherein G-CSF is produced from CHO cells.

16. A stable G-CSF formulation having a residual ratio of G-CSF of 90% or more after long-term storage testing at 25°C for 3 months or a residual ratio of G-CSF of 90% or more after long-term storage testing at 40°C for 2 months or a residual ratio of G-CSF of 90% or more after accelerated testing at 50°C for 1 month or a residual ratio of G-CSF of 90% or more after accelerated testing at 60°C for 2 weeks, characterized in that it contains one or more amino acids selected from the group consisting of lysine,

histidine, arginine, aspartic acid, glutamic acid, threonine and asparagine; and one or more amino acids selected from hydrophobic amino acids; and it has a pH of 5-7.

17. A stable G-CSF formulation having a residual ratio of G-CSF of 90% or more after long-term storage testing at 25°C for 3 months or a residual ratio of G-CSF of 90% or more after long-term storage testing at 40°C for 2 months or a residual ratio of G-CSF of 90% or more after accelerated testing at 50°C for 1 month or a residual ratio of G-CSF of 90% or more after accelerated testing at 60°C for 2 weeks, characterized in that it contains one or more amino acids selected from the group consisting of lysine, histidine, arginine, aspartic acid and glutamic acid; and one or more amino acids selected from the group consisting of phenylalanine, tryptophan and leucine; and it has a pH of 5-7.

18. The G-CSF formulation of Claim 15 or 16, which has a pH of 6.5.

19. A stabilized G-CSF formulation, which does not substantially produce a variant oxidized at methionine.

20. A stabilized G-CSF formulation, which contains methionine and other one or more amino acids and does not substantially produce a variant oxidized at methionine.

21. The G-CSF formulation of Claim 19 or 20, which is substantially free from protein as a stabilizer.

22. A method for inhibiting a physiologically active protein containing a methionine residue from producing a

variant oxidized at the methionine residue, comprising adding methionine to a composition containing said protein.

23. The method of Claim 22 wherein said physiologically active protein is a cytokine or a physiologically active peptide.

24. The method of Claim 22 wherein said physiologically active protein is a colony-stimulating factor or PTH.

25. The method of Claim 22 wherein said physiologically active protein is G-CSF, erythropoietin or PTH.

26. The method of any one of Claims 22 to 25 wherein other proteins are not present as stabilizers.

27. The method of any one of Claims 22 to 26 wherein said composition containing a physiologically active protein having a methionine residue is lyophilized or in the form of a solution.

28. A stabilized composition containing a physiologically active protein having a methionine residue, further containing methionine and one or more other amino acids.

29. The composition of Claim 28 wherein said amino acid is one or more selected from the group of consisting of lysine, histidine, arginine, aspartic acid, glutamic acid, phenylalanine, tryptophan, leucine, isoleucine, valine, alanine, proline, glycine, serine, threonine, asparagine, glutamine and tyrosine.

30. The composition of Claim 28 or 29, which is substantially free from other proteins as stabilizers.